SEP 08 2009

K091921

SECTION 5. 510(k) Summary

Company Name:	Codman & Shurtleff, Inc.
Company Address:	325 Paramount Drive Raynham, MA 02767
Establishment Registration No.:	1226348
Manufacturing Facility:	Medos Sarl Rue Girardet 29 CH 2400 Le Locle, Switzerland
Establishment Registration No.:	8031062
Submitted By:	Paul Amaral 325 Paramount Drive Raynham, MA 02767

Phone Number: (508) 828-3393 Facsimile Number: (508) 828-2777

Device Proprietary Name:	Codman Slim-Line Standard Aneurysm Clip Codman Slim-Line Mini Clips Codman Slim-Line Graft Clip Codman Slim-Line Reinforcing Clip Codman Slim-Line Temporary Aneurysm Clip Codman AVM Micro Clip System
Common Name:	Aneurysm Clips
Device Classification Name:	Clip, Aneurysm
Classification Panel Name:	Neurology
FDA Panel Number:	84
Product Code:	HCH
Proposed Device Class:	HCH: Class II per 21 CFR § 882.5200 Clip, Aneurysm

Predicate Device(s): K912456 SUNDT SLIM-LINE GRAFT CLIPS
K902544 SUNDT AVM MICRO CLIP SYSTEM

Device Description: Aneurysm clips have two parts, a spring section and two blades. The spring section determines the strength of the clip. The blades grasp the aneurysm.

Intended Use:

Codman Slim Line Standard Aneurysm Clip is used for permanent occlusion of intracranial aneurysm.

Codman Slim Line Mini Clip is used for the occlusion of small vessels when controlling bleeding on arteriovenous malformations or other similar venous structures.

Codman Slim-Line Graft clip is used to encircle an artery in which a hole has developed as a result of a traumatic injury to the vessel or from an aneurysm tearing at its base that cannot be sutured as the hole is in such a position that it is difficult for the surgeon to rotate a needle.

Codman Slim-Line Reinforcing clip is used to reinforce aneurysm clips that may not be of adequate strength to occlude the aneurysm.

Codman Slim-Line Temporary Aneurysm Clip is used for the occlusion of small vessels when controlling bleeding on arteriovenous malformations or other similar venous structure.

Codman AVM Micro Clip System is designed for occlusion of small vessels when controlling bleeding on arteriovenous malformation or other smaller venous structures.

Summary of non-clinical testing: Bench testing has been completed and demonstrates that the device performs according to its description and intended use which is the same as the predicate device. All test results demonstrated the substantial equivalence of the products to the previously cleared products from the FDA and the safety and effectiveness has not been compromised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 08 2009

Codman & Shurtleff, Inc.
c/o Paul Amaral
Regulatory Affairs Sr. International Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K091921
Trade/Device Name: Codman® Aneurysm Clips, Codman® AVM Micro Clip system, Codman® Slimline Graft, Reinforcing, Mini Aneurysm Clip
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: II
Product Code: HCH
Dated: August 17, 2009
Received: August 18, 2009

Dear Mr. Amaral:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091921

Device Name: **Aneurysm Clips**

Indications For Use:
Codman Slim Line Standard Clip is used for permanent occlusion of intracranial aneurysm.

Codman Slim Line Mini Clip is used for the occlusion of small vessels when controlling bleeding on arteriovenous malformations or other similar venous structures.

Codman Slim-Line Graft clip is used to encircle an artery in which a hole has developed as a result of a traumatic injury to the vessel or from an aneurysm tearing at its base that cannot be sutured as the hole is in such a position that it is difficult for the surgeon to rotate a needle.

Codman Slim-Line Reinforcing clip is used to reinforce aneurysm clips that may not be of adequate strength to occlude the aneurysm.

Codman Slim-Line Temporary Aneurysm Clip is used for the occlusion of small vessels when controlling bleeding on arteriovenous malformations or other similar venous structure.

Codman AVM Micro Clip System is designed for occlusion of small vessels when controlling bleeding on arteriovenous malformation or other smaller venous structures.

Prescription Use: _____X_____ OR Over-The-Counter Use:_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091921